MAR - 8 2001

510(k) Summary

1. Submitter Information:

Company:	CIBA Vision Corporation 11460 Johns Creek Parkway Duluth, Georgia USA 30097
Contact Person:	Alicia M. Plesnarski, RAC Senior Specialist, Global Regulatory Affairs
Telephone:	678-415-3924
FAX:	678-415-3033
Date Prepared:	9 February, 2001

2. Device Name:

- Common Name: Soft Contact Lens
- Trade/Proprietary Name: Focus® DAILIES® Progressives (nelfilcon A) ONE-DAY CONTACT LENS
- Classification Name: Daily Wear Soft (hydrophilic) Contact Lens
- Device Classification: Class II [21 CFR 886.5925 (b) (1)]

3. Predicate Device(s):

Lens Material – CIBA Vision's Focus® DAILIES® (nelfilcon A) One-Day Contact Lens

Clear lenses: K943487
VISITINT® lenses: K984273

Multifocal Design – CIBA Vision's Focus Progressives (vifilcon A) Soft Contact Lens
Bifocal: P820021/S15
Zoom: P820021/S19

4. Description of Device:

The Focus® DAILIES® Progressives (nelfilcon A) ONE-DAY CONTACT LENS is a daily wear soft contact lens intended for single use daily disposable wear. The Focus Dailies Progressives lens is a progressive aspheric simultaneous vision soft contact lens. A constant near power profile is incorporated into each lens across the full range of distance powers. The near and intermediate powers are concentrated primarily in the central portion of the optical zone while the surrounding portion is weighted toward distance. The continuous changes in power across the surface of the lens allow patients requiring a reading addition of up to +3.00 diopters to see clearly at far, intermediate and near distances.

The lens material is 69% water and 31% nelfilcon A polymer (polyvinyl alcohol partially acetalized with N-formylmethyl acrylamide). The lenses are tinted from edge to edge for visibility purposes with the color additive copper phthalocyanine (CuP).

Lenses are supplied sterile in foil sealed blister packs containing isotonic phosphate-acetate buffered saline solution.

The physical properties of the lens are:

- Refractive Index: 1.38 (hydrated)
- Center Thickness: 0.09 to0.17 mm (0.10 at -3.00D; 0.15 at +3.00D)
- Light Transmittance: 96% (approx.)
- Oxygen Permeability (Dk): 26×10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg) [35° C, Fatt corrected]
- Water Content: 69% by weight in normal saline

5. Indications for Use:

Focus® DAILIES® Progressives (nelfilcon A) ONE-DAY CONTACT LENSES are indicated for daily wear for the optical correction of refractive ametropia (myopia or hyperopia) and/or presbyopia in not aphakic persons with non-diseased eyes who require a reading addition of +3.00 diopters (D) or less and who may have 2.00 diopters (D) or less of astigmatism that does not interfere with visual acuity.

The lenses are to be prescribed for single use daily disposable wear. DAILIES® lenses are not intended to be cleaned or disinfected and should be discarded after a single use.

6. Description of Safety and Substantial Equivalence

6.1 Comparison to Predicate Device (s):

- Lens Material [Predicate Lens spherical Focus DAILIES (nelfilcon A)]:
  Lens material, chemical composition, manufacturing process, packaging and the sterilization method and cycle remain unchanged from the descriptions provided in cleared Premarket Notification 510(k) K963487 and K984273 for clear and visitinted spherical DAILIES (nelfilcon A) lenses. The established safety profile (pre-clinical, toxicological, physical and chemical) of clear and visitinted spherical DAILIES lenses and visitinted multifocal DAILIES Progressives lenses are equivalent.

- Lens Design [Predicate Lens multifocal Focus Progressives (vifilcon A)]:
  The Focus Dailies Progressives (nelfilcon A) lens incorporates the same multifocal design used for the predicate lens Focus Progressives (vifilcon A). The multifocal design was approved for the (vifilcon A) lens material via Premarket Approval Supplements P820021/S15 and P820021/S19. Multifocal lenses are progressive aspheric simultaneous vision soft contacts. A constant near power profile is incorporated into each lens across the full range of distance powers. The near and intermediate powers are concentrated primarily in the central portion of the optical zone while the surrounding portion is weighted toward distance.

Table 1: Comparison to CIBA Vision's Predicate Device(s)

	Predicate Device(s)		
	Focus DAILIES (nelfilcon A) One-Day Contact Lenses	Focus Progressives (vifilcon A) Contact Lenses	Focus DAILIES PROGRESSIVES (nelfilcon A) One-Day Contact Lenses
Lens Material:	nelfilcon A	vifilcon A	nelfilcon A
Material Classification:	FDA Group 2 (> 50% H_2O, nonionic polymer)	FDA Group 4 (> 50% H_2O, ionic polymer)	FDA Group 2 (> 50% H_2O, nonionic polymer)
Water Content:	69%	55%	69%
Light Transmittance (approx):	96%	93%	96%
Oxygen Permeability (Dk): 35° C, Fatt corrected	26×10^{-11}	16×10^{-11}	26×10^{-11}
Power Range:	+20.00 to -20.00D	+20.00 to -20.00D	+20.00 to -20.00D
Visibility Tint:	With or without Copper Phthalocyanine	Reactive Blue 21	Copper Phthalocyanine
Manufacturing Method:	Full Mold Cast Lightstream Technology	Full Mold Cast Cure, wet processing	Full Mold Cast Lightstream Technology
Lens Design:	Spherical	Multifocal	Multifocal
Sterilization:	Steam sterilization, Validated autoclave	Steam sterilization, Validated autoclave	Steam sterilization, Validated autoclave
Packaging:	Blister Pack	Blister Pack	Blister Pack

6.2 Non-clinical Testing:

The (nelfilcon A) lens visitint formulation, production process, packaging materials, finished product specifications and sterilization method and cycle remain unchanged as described in CIBA Vision's previously described in Premarket Notification 510(k) K963487 and K984273. Please refer to the nonclinical information and reports in these prior 510(k)s that also apply to Focus DAILIES Progressives lenses.

The only change to DAILIES involves a geometry change to the front surface of the lens to incorporate the additional corrective optics. A successful manufacturing validation has been completed demonstrating production capability in producing the multifocal lens design.

6.3 Clinical Testing:

A one-month clinical study demonstrated successful transfer of the multifocal design used for Focus Progressives (vifilcon A) lenses to Focus DAILIES Progressives (nelfilcon A) lenses. No adverse reactions were observed for either the test or control lenses and no significant differences existed in overall performance of the lenses. In terms of visual performance, the multifocal design used for Focus DAILIES Progressives lenses was effective in correcting presbyopia.

7. Substantial Equivalence

Focus® DAILIES® Progressives (nelfilcon A) multifocal soft contact lenses are substantially equivalent to clear and tinted spherical Focus DAILIES (nelfilcon A) lenses and to Focus Progressives (vifilcon A) multifocal soft contact lenses in terms of lens material, physical and chemical properties, clinical performance and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 8 2001

Alicia M. Plesnarski, RAC
Senior Specialist, Global Regulatory Affairs
CIBA Vision
11460 Johns Creek Parkway
Duluth, GA 30097

Re: K003826
Trade Name: Focus DAILIES® PROGRESSIVES (nelfilcon A) ONE-DAY CONTACT LENSES (clear and visibility tinted)
Regulatory Class: II
Product Code: 86 MVN, LPL
Dated: December 8, 2000
Received: December 11, 2000

Dear Ms. Plesnarski:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

PART III. INDICATIONS FOR USE STATEMENT

510(k) Number: K003826

Device Name: Focus® DAILIES® Progressives (nelfilcon A) One-Day Contact Lens

Indications For Use:

Focus® DAILIES® Progressives (nelfilcon A) One-Day soft contact lenses are indicated for daily wear for the optical correction of refractive ametropia (myopia or hyperopia) and/or presbyopia in not aphakic persons with non-diseased eyes who require a reading addition of +3.00 diopters (D) or less and who may have 2.00 diopters (D) or less of astigmatism that does not interfere with visual acuity.

The lenses are to be prescribed for single-use daily disposable wear. DAILIES lenses are not intended to be cleaned or disinfected and should be discarded after a single use.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K003826

Prescription Use
(Per 21 CFR 801.109)

Prescription Use: ☑ or **Over the Counter Use** ☐